510(k) Summary Prepared March 4, 2014

APR 3 0 2014 K140959

1. Sponsor:

Siemens Medical Solutions, Inc.,

Ultrasound Division

685 East Middlefield Road

Mountain View. California 94043

Contact Person:

Christine Dunn

Telephone:

(425) 785-1617

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(425) 391-9161

2. Device Name:

Acuson S1000, S2000, S3000™ Diagnostic Ultrasound Systems

Common Name:

Diagnostic Ultrasound System

Classification:

Regulatory Class:

П

Review Category:

Tier II

Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550

Product Code 90-IYN

Ultrasonic Pulsed Echo Imaging System

FR # 892.1560

Product Code 90-IYO

Diagnostic Ultrasound Transducer

FR # 892.1570

Product Code 90-ITX

Diagnostic Ultrasound Catheter

FR # 870.1200

Product Code OBJ

3. Legally Marketed Predicate Devices

The modified Acuson S1000, S2000, S3000 Ultrasound Systems are substantially equivalent to the company's own systems:

System	510(k)
S1000	K132804
S2000	K132804
\$3000	K132804

4. Device Description:

The ultrasound systems are multi-purpose mobile, software controlled diagnostic ultrasound systems with and on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. The function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude, Doppler Mode, a combination of modes, or Harmonic Imaging and 3D/4D Imaging on a Flat Panel Display.

5. Intended Use

The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

6. Summary of Technological Characteristics - New Device Compared to Predicate

Feature / Characteristic	Acuson S1000/S2000 /S3000 This Submission	Acuson \$1000/\$2000 /\$3000 K# 132804
Indications for Use:		
■ Fetal	√ .	1
■ Abdominal	1	1
■ Intraoperative	√ √	1 1
Intraoperative neurological	I	ļ - I
■ Pediatric	1 ₹	1 4
■ Small Organ	1 ₹	
Neonatal cephalic	√	1 ₹
Adult Cephalic	1 1	₹.
■ Cardiac	1 ₹	1 1
■ Trans-esophageal	√.	₹
■ Transrectal	√ .	1 1
■ Transvaginal	√.	√.
Peripheral vessel	✓	✓
■ Laparoscopic		
Musculo-skeletal (conventional)	1	₹
Musculo-skeletal (superficial)	1	√
Center Frequencies Supported:		
■ 2.0 MHz	√ √	1
■ 3.0 MHz	1	1
■ 3.2 MHz	√	
■ 3.3 MHz	√ √	√
■ 4.2 MHz	√ √	√
■ 4.4 MHz	√	1

Feature / Characteristi	Acuson \$1000/\$2000 /\$3000 This Submission Acuson \$1000/\$2000 /\$3000 K# 132804
■ 4.8 MHz	1 1
■ 5.0 MHz	→ →
■ 5.2 MHz	1 1
■ 6.0 MHz	1 1
■ 6.5 MHz	1 1
■ 6.9 MHz	√
■ 9.5 MHz	1 1
■ 10.0 MHz	1 1
Modes:	
■ B	4 4
 Parallel processing in B m 	ode / 1
■ M	4 4
■ PWD (Pulsed Wave Dopp	er) $\sqrt{}$
CWD (Continuous Wave I	
D (Color Doppler)	4 4
Amplitude Doppler	4 4
Combined (BMDC)	4 4
Features:	
Quad processing in color	1 1
Ī	magina V
Transco dosas marmonis	
олессаро рапоганно на	aging \
imaging	
■ 3-Scape™ real-time 3D ima	ging v
fourSight™ 4D transducer technology	1 1
■ TEQ™ ultrasound technolo	у 1 1
 Cardiac Imaging physiological signal displ 	
syngo ® Auto OB measurer	nents 1
■ Advanced SieClear™ spatial compounding	1 1
STIC (Fetal Heart Imaging)	1 1
 Amnioscopic rendering 	1 1
Cadence contrast agent im-	ging $\sqrt{}$
■ Clarify [™] vascular enhance technology	
eSie™ Touch elasticity ima	ing 1
syngo ® Auto Left heart	1 1
syngo ® Velocity Vector Im	aging V
Semi Auto-segmentation (e	
Calc) Custom Tissue Imaging / S Sound	eed of 🗸
■ AHP	1 1
eSie Fusion (S3000 only)	1 1

Feature / Characteristic	Acuson S1000/S2000 /S3000 This Submission	Acuson \$1000/\$2000 /\$3000 K# 132804
■ VTI (S2000 & S3000 only)	4	4
Wireless	√	√ √
Monitor: 21" FPD	4	
Output Display Standard (Track 3)	1	7
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1
UL 60601-1 Certified	1	1
Indications for Use	√ √	٧

7. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- UL 60601-1; Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN/IEC 60601-1
 - EN/IEC 60601-1-1
 - EN/IEC 60601-1-2
- ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged.

Additional testing was performed to verify the software release as well as transducer and wireless performance.

8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the \$1000, \$2000, \$3000 systems use the same technology and principles as existing devices, clinical data is not required.

9. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Siemens Medical that the S1000, S2000 and S3000 systems are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

April 30, 2014

Siemens Medical Solutions USA, Inc. % Mark Job Responsible Third Party Official Regulatory Technology Services, LLC. 1394 25th Street NW BUFFALO MN 55313

Re: K140959

Trade/Device Name: Acuson S1000, S2000, S3000 Diagnostic Ultrasound Systems

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX, OBJ

Dated: April 14, 2014 Received: April 15, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson S1000, S2000, S3000 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

121.4	CW2 Probe	CW5 Probe
EC9-4 Curved Array	MC9-4 Curved Array	9L4 Linear Array
14L5 Multi-D Array	4P1 Phased Array	6C2 Curved Array
4C1 Curved Array	6C1HD Curved Array	8C3HD Curved Array
4VI Phased Array	10V4 Phased Array	14L5 SP Linear Array
9EVF4 Curved Array	V5Ms Multiplane TEE	18L6 HD Linear
Array8V3 Phased Array	4V1c Phased Array	6L3
FV8C4	V7M TEE	

7CF2 Curved array mechanical 3D
AcuNav 8F Ultrasound Catheter
AcuNav 10F Ultrasound Catheter

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris

Director

Division of Radiological Health Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

for

Enclosure

1.3 Indications for Use

A. 510(k) Number (if known): K140959

Device Name: S1000, S2000, S3000 Diagnostic Ultrasound Systems

Indications for Use:

The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures (fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac) and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

Prescription UseX (Part 21CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE	BELOW THIS LINE	-CONTINUE ON A SEPARATE PAGE IF NEEDED
Concurrence of	of Center for Devices and	Radiological Health (CDRH)
Concurrence of Center for Devices and	Radiological Health (CD	RH) (Signature)
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1,3 Indications for Use Forms

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K140959

Device Name: Intended Lice: ACUSON S1000, S2000, S3000 Ultrasound System

Ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use:		با	utrasc	ouna im	aging o	T TIUID HOW	analysis of	me numai	1 Dody as to	IIOWS.
		Mode of Operation								
Clinical Application	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic			Ī —							
Fetal		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Abdominal		Ρ	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 13, 16, 18
Intraoperative (Note 9)		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Intraoperative Neurological										
Pediatric		Р	Р	Р	Р	Р	Р		вмос	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		Р	Р	Р	Р	Р	P		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16, 18
Neonatal Cephalic		P	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		Р	Р	P	Р	, Р	Р		ВМОС	Note 2,3,4,5,7,8,10
Cardiac		Р	Р	P	Р	P	Р		BMDC	Note 2,3,4,5,6,7,8,10,15
Trans-esophageal		Р	Р	Р	Р	Р	P		BMDC	Note 4
Transrectal		Р	P	P		Р	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Transvaginal		Р	Р	P		Р	P	_	BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral	 		†							
Intravascular										11-1-00-450-7040
Peripheral vessel		Р	P	Р	Р	Р	Р		BMDC	Note2,3,4,5,6,7,8,10 11,14,15
Laparoscopic			L		<u> </u>		 -	└ ─	 	Note 2.2.4.5.7.9.40
Musculo-skeletal Conventional		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14, 18
Musculo-skeletal Superficial		P	Р	P	Р	Р	P		BMDC	Note 2,3,4,5,7,8,10, 11,14, 18
Other (specify) Neonatal Cardiac		P	P	Р	P	Р	Р		BMDC	Note 3,4,6, 10

N = new indication; P = previously cleared by FDA K 132804

i.e. breast, testes, thyrold, penis, prostate, etc. Note 1 Tissue Equalization Technology

Note 4 Note 7 B&W SieScape panoramic Imaging Clarify VE vascular enhancement technology eSie Touch elasticity imaging / FTI Note 10

eSie Fusion VTI Note 17

Note 18

Note 2 Ensemble tissue harmonic imaging Note 5 3-Scape real-time 3D imaging Note 8 Power SieScape penoramic imaging

Note 11 Advanced Sieclear spatial compounding

Note 15 AHP

Note 3 SieClear multi-view spatial compounding Note 6 Cadence contrast agent imaging

Note 9 For example: vascular, abdominal

Note 13 STIC

Note 16 Custom Tissue Imaging

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510 (k) Number (if known): K140959

Device Name: Intended Use:

12L4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound imaging or fluid flow analysis of the human body as follows:

	T	Mode of Operation								
Clinical Application	А	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal	Ι									
Abdominal		l								
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16
Small Organ (Note 1)		N	Ν	N		N	N		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16
Neonatal Cephalic]					
Adult Cephalic										
Cardiac		Γ								
Trans-esophageal	\top									
Transrectal									<u> </u>	
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		N	N	N		N	N		BMDC	Note 2,3,4,5, 7,8,10 11, 14
Laparoscopic		1								
Musculo-skeletal Conventional		N	N	N	:	N	N		BMDC	Note 2,3,4,5,7,8,10 11, 14
Musculo-skeletal Superficial										,
Other (specify)	1	Γ	T						1	

N = new indication; P = previously cleared by FDA K123001

Additional	Comments:

For example: breast, testes, thyroid, penis, prostate, etc. Note 1

SieClear multi-view spatial compounding Note 3

3-Scape real-time 3D imaging Note 5

B&W SieScape panoramic imaging Note 7

Note 10 Clarify VE vascular enhancement technology

compounding/DTCE

Note 14 eSie™ Touch elasticity imaging

Note 2 Ensemble tissue harmonic ima	agir	n
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Tissue Equalization Technology Note 4

Cadence contrast agent imaging Note 6 Power SieScape panoramic imaging

Note 8 Note 11 Advanced Sieclear spatial

Note 16 Custom Tissue Imaging /FTI

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510 (k) Number (if known): K140959

Device Name:

CW2 Probe For Use On ACUSON S1000, S2000, S3000 Ultrasound System

Ultrasound imaging or fluid flow analysis of the human body as follows

Intended Use:		L	lltrasc	ound im	aging o	r fluid flow	ow analysis of the human body as follows:						
						M	ode of Opera	ation					
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)			
Ophthalmic													
Fetal					Р								
Abdominal					Р								
Intraoperative (Note 9)					Р								
Intraoperative Neurological	ļ <u> </u>												
Pediatric					Р				<u> </u>				
Small Organ (Note 1)					Р								
Neonatal Cephalic					Р								
Adult Cephalic		L			P				<u> </u>				
Cardiac		<u> </u>			Р		ļ		<u> </u>				
Trans-esophageal		L	ļ <u>.</u>		ļ		ļ		ļ				
Transrectal													
Transvaginal	<u> </u>	<u> </u>	<u> </u>										
Transurethral	<u>L</u>		<u> </u>	<u> </u>			ļ			<u></u>			
Intravascular			<u> </u>				<u> </u>	ļ <u></u> -	 -				
Peripheral vessel	<u> </u>	L	<u> </u>		P_				-				
Laparoscopic					<u> </u>	ļ			 				
Musculo-skeletal Conventional					Р								
Musculo-skeletal Superficial					P								
Other (specify)						<u> </u>	<u> </u>	<u> </u>					

N = new indication; P = previously cleared by FDA K# 132804

Additional Co	omments
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Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 9 For example: vascular, abdominal

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510 (k) Number (if K 140959

known):

Device Name:

CW5 Probe For Use On ACUSON S1000, S2000, S3000 Ultrasound System

tended Use:	Ultrasound imaging or fluid flow analysis of the human body as follows:										
						Mo	ode of Opera	ation			
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic	ĭ		I		[<u> </u>		
Fetal				[<u></u>	Р						
Abdominal					Р						
Intraoperative (Note 9)					Р						
Intraoperative Neurological					Р						
Pediatric]	Р						
Small Organ (Note 1)					Р						
Neonatal Cephalic					Р				ļ <u> </u>		
Adult Cephalic				<u> </u>	Р						
Cardiac				i	Р						
Trans-esophageal									<u> </u>		
Transrectal									-		
Transvaginal											
Transurethral							ļ				
Intravascular											
Peripheral vessel					Р						
Laparoscopic				L							
Musculo-skeletal Conventional					Р						
Musculo-skeletal Superficial					Р						
Other (specify)									<u> </u>		

N = new indication; P = previously cleared by FDA K#132804

Additional	Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 9 For example: vascular, abdominal

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)	
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510 (k) Number (if known): K 140959

Device Name:

EC9-4 Curved Array Transducer For Use On ACUSON S1000, S2000, S3000 Ultrasound

System

ntended Use:		Ultras	sound	l imagin	g or flui	d flow ana	lysis of the	human bo	dy as follow	s:
	Ī						Mode of Op	eration		
Ctinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				T						
Fetal		Р	Р	P		P	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		Р	Р	Р		Р	Ρ.		BMDC	Note 2,3,4,5,6,,7,8,10, 11,
Intraoperative										
Intraoperative Neurological										
Pediatric						L			ļ	
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC:	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		Р	Ъ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Adult Cephalic	Γ		I							
Cardiac				<u> </u>					<u> </u>	
Trans-esophageal			<u> </u>	<u> </u>						14 14 00 45 0 70 40
Transrectal		Р	P	P		Р	P		BMDC	Note 2,3,4,5, 6, 7,8,10, 11,14
Transvaginal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral									<u> </u>	
Intravascular									ļ	
Peripheral vessel									<u> </u>	
Laparoscopic									<u> </u>	
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		Ţ					<u></u>		1	l

N = new indication; P = previously cleared by FDA K# 132804

Additional	Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

SieClear multi-view spatial compounding Note 3

Note 5 3-Scape real-time 3D imaging Note 7 B&W SieScape panoramic imaging

Note 11 Advanced Sieclear spatial compounding

Note 14 eSie™ Touch elasticity imaging / FTI

Note 2 Ensemble tissue harmonic imaging

Note 4 Tissue Equalization Technology

Note 6 Cadence contrast agent imaging
Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED)

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510 (k) Number (if known): K140959

Device Name:

MC9-4 Curved Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation										
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Р	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11		
Abdominal		P	Р	P		Р	P		BMDC	Note 2,3,4,5,6,,7,8,10, 11,		
Intraoperative Note 9										•		
Intraoperative Neurological												
Pediatric			L					<u> </u>	ļ			
Small Organ (Note 1)		Р	P	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14		
Neonatal Cephalic		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10		
Adult Cephalic				_								
Cardiac			Ī.,									
Trans-esophageal	Τ				<u> </u>							
Transrectal		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5, 6, 7,8,10, 11,14		
Transvaginal		Ρ	Р	Р		Р	Ρ		BMDC	Note 2,3,4,5,7,8,10, 11		
Transurethral												
Intravascular												
Peripheral vessel							<u> </u>	ļ				
Laparoscopic				<u> </u>			ļ <u> </u>					
Musculo-skeletal Conventional								-				
Musculo-skeletal Superficial												
Other (specify)	T							L	<u></u>			

N = new indication; P = previously cleared by FDA K# 132804

10 How more and a present a	•			
Additional Comments: Note 1 For example: breast, testes. Note 3 SieClear multi-view spatial of SieClear spatial of SieClea	compounding ng maging compounding	Note 14	Ensemble tissue harmonic imaging Tissue Equalization Technology Cadence contrast agent imaging Power SieScape panoramic imaging Clarify VE vascular enhancement techno eSie™ Touch elasticity imaging / FTI INUE ON A SEPARATE PAGE IF NEEDED)	logy
Concurrence of Center for Devices	Concurrence of Center for Dev			
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510 (k) Number (if known): K140959

Device Name:

9L4 Linear Array Transducer For Use On ACUSON S1000, S2000, S3000 Ultrasound

Systems

The state of the second second

Intended Use:	Ultrasound imaging or fluid flow analysis of the human body as follows:										
							Mode of C	peration			
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11	
Abdominal				<u> </u>					ļ		
Intraoperative Note 9 Intraoperative					·			-····	-		
Neurological	<u> </u>					P	P		BMDC	Note 2,3,4,5,7,8,10, 11	
Pediatric	ļ	Р	Р	Р		<u> </u>	P		·	Note 2,3,4,5,6,7,8,10, 11,14.	
Small Organ (Note 1)		P	Ρ	Р		Р	Р		BMDC	16, 18	
Neonatal Cephalic		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10, 11	
Adult Cephalic		Р	P	Р		Р	Р				
Cardiac		Р	Р	Р		Р	Р		BMDC	Note 15	
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral								,			
Intravascular		<u> </u>	<u> </u>							11 1 2 2 4 5 6 7 8 4 9 4 4	
Peripheral vessel		₽	Р	Р		Р	Р		BMDC	Note 2,3,4,5,6, 7,8,10, 11, 14,15	
Laparoscopic											
Musculo-skeletal Conventional		Þ	Р	Р		Р	Р		BMDC	Note 2,3,4,5,6,7,8,10, 11, 14	
Musculo-skeletal Superficial		Р	Р	Р		P	Р		вмос	Note 2,3,4,5,6,7,8,10, 11, 14	
Other (specify)									<u> </u>		

N = new indication; P = previously cleared by FDA K#132804

Additional Comments:

For example: breast, testes, thyroid, penis, prostate, etc. Note 1

SieClear multi-view spatial compounding

Note 5 3-Scape real-time 3D imaging

B&W SieScape panoramic imaging Note 7

Abdomen and Vascular Note 9

Note 11 Advanced Sieclear spatial compounding

Note 18 VTI (Virtual Touch Imaging)

Ensemble tissue harmonic imaging

Note 2 Tissue Equalization Technology

Note 4 Cadence contrast agent imaging Note 6

Power SieScape panoramic imaging Note 8

Note 10 Clarify VE vascular enhancement technology

Note 14 eSie™ Touch elasticity imaging / FTI

Note 16 Custom Tissue Imaging

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510 (k) Number (if known): K140959

Device Name:

14L5 Multi-D Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Intended Lice: Ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use:		Ultrasound imaging or fluid flow analysis of the human body as follows:											
		Mode of Operation											
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)			
Ophthalmic				<u> </u>									
Fetal						_							
Abdominal										,			
Intraoperative Note 9					:								
Intraoperative Neurological													
Pediatric													
Small Organ (Note 1)		Р	Р	Р		Р	Р		вмрс	Note 2,3,4,5,7,8,10, 11, 14, 16			
Neonatal Cephalic													
Adult Cephalic	T												
Cardiac									ļ				
Trans-esophageal		İ											
Transrectal													
Transvaginal				L									
Transurethral													
Intravascular													
Peripheral vessel		Р	P	P		Ρ	· P		BMDC	Note 2,3,4,5,6, 7,8,10, 11, 14			
Laparoscopic													
Musculo-skeletal Conventional		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10 11, 14			
Musculo-skeletal Superficial								****					
Other (specify)													

N = new indication; P = previously cleared by FDA K# 132804

For example: breast, testes, thyroid, penis, prostate, etc. SieClear multi-view spatial compounding Note 1

Note 3

3-Scape real-time 3D imaging Note 5

Note 7 **B&W SieScape panoramic imaging** Note 9 Abdomen and Vascular

technology

Note 11 Advanced Sieclear spatial compounding

Note 16 Custom Tissue Imaging

Ensemble tissue harmonic imaging Note 2

Note 4 Tissue Equalization Technology

Note 6 Cadence contrast agent imaging

Power SieScape panoramic imaging Note 8

Note 10 Clarify VE vascular enhancement

Note 14 eSie™ Touch elasticity imaging / FTI

Note 18 Virtual Touch Imaging

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510 (k) Number (if known): K140959

Device Name:

4P1 Phased Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use:	Ultrasound imaging or fluid flow analysis of the fluintari body as follows. Mode of Operation									
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		[14.
Fetal		Р	Р	Р	Р	Ρ	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal		Р	Р	Р	Р	ρ.	Р		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Note 9	· .									
Intraoperative Neurological							:			
Pediatric										
Small Organ				<u> </u>	<u> </u>					
Neonatal Cephalic										
Adult Cephalic		Ρ	Ρ	Р	Р	Р	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac		Р	Ρ	Ρ	Р	P	Р		BMDC	Note 2,3,4,5,6,7,8,10
Trans-esophageal										<u> </u>
Transrectal					<u> </u>				<u> </u>	
Transvaginal										
Transurethral	Γ									
Intravascular										
Peripheral vessel				<u> </u>						
Laparoscopic					ļ <u> </u>					
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

Note 2	Ensemble tissue narmonic imaging
Note 3	SieClear multi-view spatial compounding
Note 4	Tissue Equalization Technology
Note 5	3-Scape real-time 3D imaging
Note 6	Cadence contrast agent imaging
Note 7	B&W SieScape panoramic imaging
Note 8	Power SieScape panoramic imaging
Note 9	Abdomen and Vascular

Note 10 Clarify VE vascular enhancement technology

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510 (k) Number (if known): K140959

Device Name:

6C2 Curved Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Ultrasound imaging or fluid flow analysis of the human body as follows: Intended Lise:

Intended Use:	1	Ultrasound imaging or fluid flow analysis of the human body as follows. Mode of Operation										
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10,		
Abdominal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16, 17		
Intraoperative Note 9												
Intraoperative Neurological												
Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11		
Small Organ							<u> </u>					
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Trans-esophageal					<u> </u>							
Transrectal				<u> </u>	<u> </u>							
Transvaginal												
Transurethral			İ			<u> </u>						
Intravascular		1	ĺ .									
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11		
Laparoscopic							<u> </u>					
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)						l			1			

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

Note 2 Ensemble tissue harmonic imaging Note 4 Tissue Equalization Technology

B&W SieScape panoramic imaging

Note 7 Note 9 Abdomen and Vascular

Note 11 Advanced Sieclear spatial compounding

Note 16 Custom Tissue Imaging

SieClear multi-view spatial compounding Note 3

Note 5 3-Scape real-time 3D imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology Note 14 eSie™ Touch elasticity imaging / FTI

Note 17 eSie Fusion

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510 (k) Number (if known): K140959

Device Name:

4C1 Curved Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

<u></u>	Mode of Operation										
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic										•	
Fetal		Р	P	Р	P	Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11	
Abdominal		Р	Ρ	Р	Ρ	Р	P		вмос	Note2,3,4,5,6,7,8, 10, 11, 14, 16, 17, 18	
Intraoperative Note 9											
Intraoperative Neurological											
Pediatric											
Small Organ		Р	Р	Р	P	Р	P		BMDC		
Neonatal Cephalic											
Adult Cephalic											
Cardiac		Ρ	P	Р	P	Ρ	P		BMDC		
Trans-esophageal											
Transrectal										,	
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		Р	Р	Р	P	Р	Р		BMDC		
Laparoscopic					<u> </u>				ļ <u> </u>		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)									L		

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

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510 (k) Number (if known): K140959

Device Name:

6C1HD Curved Array Transducer For Use On ACUSON S2000, S3000 Ultrasound

Systems

Intended Use:	Ultrasound imaging or	fluid flow analysis of	of the human bod	y as follows:

Intended Use:	Ultrasound imaging or fluid flow analysis of the human body as follows:									
		Mode of Operation								
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р	Р	Р	Р		вмос	Note 2,3,4,5,7,8,10, 11
Abdominal	-	P	Р	Р	Р	Р	Р		BMDC	Note2,3,4,5,6,7,8, 10, 11, 14, 16, 17, 18
Intraoperative Note 9										
Intraoperative Neurological										
Pediatric									<u> </u>	
Small Organ		Р	Ρ_	Р	Р	Р	Р		BMDC	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		Р	Ρ	Р	Р	Р	P		BMDC	
Trans-esophageal										
Transrectal									<u> </u>	
Transvaginal										
Transurethral									<u> </u>	
Intravascular	<u> </u>									
Peripheral vessel		Р	Р	Р	Р	Р	Р		BMDC	
Laparoscopic										
Musculo-skeletal Conventional					٠					
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

Note 8 Note 10	Ensemble tissue harmonic imaging Tissue Equalization Technology Cadence contrast agent imaging Power SieScape panoramic imaging Clarify VE vascular enhancement technology eSie™ Touch elasticity imaging / FTI	Note 5 Note 7 Note 9 Note 11 Note 16	Abdomen and Vascular Advanced Sieclear spatial compounding Custom Tissue Imaging
	eSie™ Touch elasticity imaging / F t1	Note 18	

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510 (k) Number (if known): K140959

Device Name:

8C3HD Curved Array Transducer For Use On ACUSON S2000, S3000 Ultrasound

Systems

Ultrasound imaging or fluid flow analysis of the human body as follows: Intended Lise:

						Me	ode of Opera	ation	_	
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10,
Abdominal		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16
Intraoperative Note 9										
Intraoperative Neurological										
Pediatric		ρ	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10,
Small Organ		Ρ	Р	P		Р	. Р		BMDC	
Neonatal Cephalic	T								<u> </u>	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral	Ι									
Intravascular					<u> </u>					
Peripheral vessel		Р	Р	Р		P	Р		вмос	Note 2,3,4,5,7,8,10, 11
Laparoscopic					ļ					
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		ĺ						l		

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

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SieClear multi-view spatial compounding Note 2 Ensemble tissue harmonic imaging Note 3 3-Scape real-time 3D imaging Note 5 Tissue Equalization Technology Note 4 **B&W SieScape panoramic imaging** Note 6 Cadence contrast agent imaging Note 7 Note 10 Clarify VE vascular enhancement technology Note 8 Power SieScape panoramic imaging Note 14 eSie Touch elasticity imaging / FTI Note 11 Advanced Sieclear spatial compounding

Note 16 Custom Tissue Imaging

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510 (k) Number (if known): K140959

Device Name:

4V1 Phased Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

d Use:	Ultra	Sound	ımaç	jing or	ilula no	w allalysis	or the num	air oody as	10110473.	
						Mo	ode of Opera	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10. 14, 16, 17
Intraoperative										
Intraoperative Neurological										
Pediatric			<u> </u>							
Small Organ									<u> </u>	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal							ļ			
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel .	l		<u>_</u>							
Laparoscopic			L	_					ļ	
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)									<u> </u>	

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

 Note 2
 Ensemble tissue harmonic imaging
 Note 3
 SieClear multi view spatial compounding

 Note 4
 Tissue Equalization Technology
 Note 5
 3-Scape real-time 3D imaging

 Note 7
 B&W SieScape panoramic imaging
 Note 8
 Power SieScape panoramic imaging

 Note 10
 Clarify VE vascular enhancement technology
 Note 11
 Advanced Sieclear spatial compounding

 Note 14
 eSie™ Touch elasticity imaging / FTI
 Note 16
 Custom Tissue Imaging

Note 17 eSie Fusion

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510 (k) Number (if known): K140959

Device Name:

10V4 Phased Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

d Use:	Ultra	soun	<u>d ima</u>	ging or	fluid flo	w analysis	of the hum	an body a	s follows:	
						M	lode of Oper	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		Р	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		Р	Р	Р	Р	Р	Р		BMDC	Note 3,4
Trans-esophageal							ļ			
Transrectal										
Transvaginal			ļ. <u>. </u>							
Transurethral				<u>L</u>			1		<u> </u>	·
Intravascular			<u> </u>				ļ			
Peripheral vessel		Р	P	Р	Р	Р	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic				<u>L</u>			ļ			
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)						L	<u> </u>	ļ. <u></u>	<u> </u>	

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

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510 (k) Number (if known): K140959

Device Name:

14L5 SP Linear Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Ultrasound Systems

Third flow analysis of the human body as follows:

Indications For Use:		D	iagno	stic ima	aging or	fluid flow	analysis of	the human	body as fol	liows:
		Mode of Operation								
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 9)		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10,11
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		Р	Ρ	Р		Р	Р	_ •	BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic							_			
Adult Cephalic										
Cardiac		Р	Р	P		Р	Р		BMDC	Note 15
Transesophageal										
Transrectal										
Transvaginal				ļ						
Transurethral										
Intravascular							ļ <u> </u>			Note 2 2 4 5 6
Peripheral vessel		Р	Р	Р		Р	P .		BMDC	Note2,3,4,5,6 ,7,8,10, 11,14,15
Laparoscopic									<u> </u>	
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial										
Other (specify)									<u> </u>	

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments	Addition	al i	Con	nme	nts
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For example: breast, testes, thyroid, penis, prostate, etc. Note 1

Note 3 SieClear multi-view spatial compounding 3-Scape real-time 3D imaging

Note 5 Note 7 B&W SieScape panoramic imaging

Note 9 For example: vascular, abdominal

Note 11 Advanced Sieclear spatial compounding

Note 15 AHP

Note 2 Ensemble tissue harmonic imaging

Note 4 Tissue Equalization Technology Note 6 Cadence contrast agent imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology Note 14 eSie™ Touch elasticity imaging / FTI

Note 16 Custom Tissue Imaging

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510 (k) Number (if known): K140959

Device Name:

7CF2 Curved array mechanical 3D transducer For Use On ACUSON S1000, S2000,

S3000 Ultrasound Systems

Intended Lise: Ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use:	T 	UILI	asou	no imaç	ing or i				ooy as loll	J113.
						M	ode of Oper	ation		
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		a	Р		BMDC	Note 2,3,4,5,7,8,10, 11,13
Abdominal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic							<u></u>			
Adult Cephalic										
Cardiac	T									
Trans-esophageal										
Transrectal					<u> </u>					
Transvaginal				L						
Transurethral									ļ	
Intravascular		Ĺ								
Peripheral vessel		L	<u> </u>		<u> </u>					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)							l			

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

Note 2	Ensemble	tissue	harmonic	imaging	
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Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology Note 11 Advanced Sieclear spatial compounding

Note 13 STIC

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510 (k) Number (if known): K140959

Device Name:

7CF1 Curved array mechanical 3D transducer For Use On ACUSON S1000, S2000,

S3000 Ultrasound Systems

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use:		Ultrasound imaging or fluid flow analysis of the human body as follows:								
		Mode of Operation								
Clinical Application	Α	В	M	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		1								
Fetal		Р	Р	P		P	Р		BMDC	Note 2,3,4,5,7,8,10, 11,13
Abdominal		Р	Р	Р		Р	Р		вмос	Note 2,3,4,5,7,8,10, 11, 13
Intraoperative										
Intraoperative Neurological						_			,	
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal				<u></u>						
Transrectal							ļ <u> </u>			
Transvaginal				<u> </u>						
Transurethral										
Intravascular]								
Peripheral vessel										
Laparoscopic		<u> </u>								· · · · · · · · · · · · · · · · · · ·
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

Note 11 Advanced Sieclear spatial compounding

Note 13 STIC

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510 (k) Number (if known): K140959

Device Name:

9EVF4 Curved Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of O								ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5.7,8, 10,11, 13
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic		Р	Р	Р		Р	P		8MDC	Note 2,3,4,5,7,8, 10,11
Adult Cephalic									ļ	
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8, 10,11
Transurethral										
Intravascular										
Peripheral vessel				<u> </u>					1	
Laparoscopic			ļ <u> </u>	<u> </u>					1	
Musculo-skeletal Conventional				<u></u>						
Musculo-skeletal Superficial									·	,
Other (specify)	1									

N = new indication; P = previously cleared by FDA K# 132804

Addit	ional	Com	ments:

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic Imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

Note 11 Advanced Sieclear spatial compounding

Note 13 STIC

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510 (k) Number (if known): K140959

Device Name:

V5Ms Multiplane TEE Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Ultrasound imaging or fluid flow analysis of the human body as follows: Intended Use:

Intended Use:	T	Mode of Operation								
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	1									
Fetal				_						
Abdominal	Ι									
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic									<u> </u>	
Adult Cephalic										
Cardiac										
Trans-esophageal		Р	P	Р	Р	Ρ	Ρ		BMDC	Note 4
Transrectal										
Transvaginal										
Transurethral									ļļ	
Intravascular	Π									<u> </u>
Peripheral vessel									ļļ	
Laparoscopic									L	
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)			<u> </u>	l			<u> </u>		<u> </u>	

N = new indication; P = previously cleared by FDA K# 132804

Additional	Comments:	

Note 4 Tissue Equalization Technology

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Concurrence of Center for Devices and Radiological Health (CDRH)

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510(k)_				

510 (k) Number (if known): K 140959

Device Name:

18L6 HD Linear Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

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eging or fluid flow analysis of the human body as follows:

Intended Use:		Ultrasound imaging or fluid flow analysis of the human body as follows:								
		Mode of Operation								
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative									ļ <u>.</u>	
Intraoperative Neurological										
Pediatric										N
Small Organ (Note 1)		Р	Р	Р		Р	ρ		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic										
Adult Cephalic										
Cardiac		Р	Р	Р		Р	Р		BMDC	Note 15
Trans-esophageal			<u></u>							
Transrectal	<u> </u>	<u> </u>	<u> </u>		<u></u>				<u> </u>	
Transvaginal									<u> </u>	,
Transurethral		<u> </u>		<u> </u>	ļ				<u> </u>	
Intravascular		<u> </u>							ļ	Nata 2 2 4 5 7 9 10
Peripheral vessel		P	Р	Р		Р	Р		вмос	Note 2,3,4,5,7,8,10, 11,14,15
Laparoscopic								ļ		11
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14
Other (specify)	1	1							1	

N = new indication: P = previously cleared by FDA K081148, K082142, K090334, K093812, K111674, K121138

Additional	Comments:
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Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

SieClear multi-view spatial compounding Note 3 3-Scape real-time 3D imaging

Note 5 Note 8 Power SieScape panoramic imaging

Note 11 Advanced Sieclear spatial compounding

Note 15 AHP

Note 2 Ensemble tissue harmonic imaging

Tissue Equalization Technology Note 4

Note 7 B&W SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology Note 14 eSie™ Touch elasticity imaging

Note 16 Custom Tissue Imaging/FTI

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K140959

Device Name:

8V3 Phased Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal										
Intraoperative	1									
Intraoperative Neurological										
Pediatric	1	Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Small Organ	I^-									
Neonatal Cephalic		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic			1							•
Cardiac	1	Р	Р	P	Р	Р	P		BMDC	Note 3,4,6
Trans-esophageal	Ī									
Transrectal										
Transvaginal										
Transurethral										
Intravascular							<u> </u>			
Peripheral vessel										
Laparoscopic									<u> </u>	
Musculo-skeletal Conventional								_		
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		Р	Р	Р	Р	Р	Р		вмос	Note 3,4,6

N = new indication; P = previously cleared by FDA K# 132804

Additional Comments:

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 4

Note 5 3-Scape real-time 3D imaging

Note 6 Cadence contrast agent imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

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Concurrence of Center for Devices and Radiological Health (CDRH)

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510 (k) Number (if known): K140959

Device Name:

4V1c Phased Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Liltrasound imaging or fluid flow analysis of the human body as follows: Intended Heat

Intended Use:	Ultrasound imaging or fluid flow analysis of the numan body as follows.									
		Mode of Operation								
Clinical Application	A	8	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р	Р	Р	Ρ.		BMDC	Note 2 3 4 5 7 8 10
Abdominal		Р	P	Р	P	Р	Р		BMDC	Note 2 3 4 5 7 8 10
Intraoperative		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10
Intraoperative Neurological		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10
Pediatric		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10
Small Organ										
Neonatal Cephalic										
Adult Cephalic		Р	Р	P	Р	P	Р		BMDC	Note 2 3 4 5 7 8 10
Cardiac		P	Р	Р	Р	Р	P		BMDC	Note 2 3 4 5 7 8 10 15
Trans-esophageal			<u> </u>							
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10 15
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		Р	Р	Р	Р	P	Р		BMDC	Note 2 3 4 5 7 8 10

N = new indication; P = previously cleared by FDA K# $^{\circ}$ s 132804 Additional Comments:

Note 2	Ensemble	tissue	harmonic	imaging
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Note 15 AHP

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Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging Note 6 Cadence contrast agent imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

, 510 (k) Number (if known): K140959

Device Name:

6L3 Transducer For Use On ACUSON S1000, S2000, S3000 Ultrasound Systems

Litrasound imaging or fluid flow analysis of the human body as follows:

Intended Use:	Ultrasound imaging or fluid flow analysis of the human body as follows:									
		Mode of Operation								
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р	Р	Р	Р		ВМІЖ	Note 2 3 4 5 7 8 10, 11
Abdominal										
Intraoperative Note 9		Р	Р	Р	Р	Р	Р		ВМІХ	Note 2 3 4 5 7 8 10, 11
Intraoperative Neurological										-
Pediatric	· ·									
Small Organ		Р	Р	Р	P	P	Р		вміх	Note 2 3 4 5 7 8 10, 1
Neonatal Cephalic										
Adult Cephalic										
Cardiac		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10 15
Trans-esophageal									ļ	-
Transrectal		L .								
Transvaginal					1	<u> </u>				
Transurethral									ļ. —	
Intravascular									133 47343	00457040
Peripheral vessel		P	P	Р	Р	Р	Р		BMDC-	Note 2 3 4 5 7 8 10, 11 15
Laparoscopic									40.47.6	
Musculo-skeletal Conventional		P	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10, 11
Musculo-skeletal Superficial		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10.
Other (specify)						l			<u> </u>	

N = new indication; P = previously cleared by FDA K#'s132804

Additional	Comments:

Note 2 Ensemble tissue harmonic imaging

Note 4 Tissue Equalization Technology Note 6 Cadence contrast agent imaging

Note 8 Power SieScape panoramic imaging

Note 11 Advanced Sieclear spatial compounding

Note 3 SieClear multi-view spatial compounding

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

Note 15 AHP

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510 (k) Number (if known); K 140959

Device Name:

EV8C4 Transducer For Use On ACUSON S1000, S2000, S3000 Ultrasound

Systems

Intended Lis gion or fluid flow analysis of the human body as follows:

Intended Use:		Ultrasound imaging or fluid flow analysis of the human body as follows:								
		Mode of Operation								
Clinical Application	Α	8	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р	Р	Р	P		BMDC	Note 2 3 4 5 7 8 10
Abdominal		Р	Р	P	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10
Intraoperative				Ĺ						
Pediatric	Ι		Ĺ							
Small Organ										
Neonatal Cephalic										
Adult Cephalic					<u></u>				ļ	
Cardiac										
Trans-esophageal	I				<u> </u>					
Transrectal										
Transvaginal		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 6 7 8 10
Transurethral										
Intravascular						<u>. </u>				
Peripheral vessel	<u> </u>								<u> </u>	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K#'s 132804

Additional Comments:

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

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510 (k) Number (if known):

K140959

Device Name:

V7M TEE Transducer For Use On ACUSON S1000, S2000, S3000 Ultrasound

Systems

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	А	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) *	Harmonic Imaging	Other (Specify)
Ophthalmic						1			-		
Fetal											
Abdominal	 	P	P	Р	Р	Р	Р		Р	Р	Note 4
Intraoperative	 										
Intraoperative Neurological											
Pediatric	<u> </u>	Р	Ρ	Р	Р	Р	Р		Р	Р	Note 4
Small Organ (specify)**											
Neonatal Cephalic											
Adult Cephalic	1										
Cardiac		Р	Р	Р	Р	Р	P		P	Р	Note 4
Trans-esophageal		Р	۵.	Р	Р	Р	P		Р	Р	Note 4
Transrectal											
Transvaginal						Ĭ			<u> </u>		
Transurethral											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal (Conventional)											
Musculo-skeletal (Superficial)											
Other (specify)											

P=previously cleared by the FDA under premarket notifications #K132804

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Dop B+Clarify VE

Note 2 Ensemble tissue harmonic imaging

Note 4 Tissue Equalization Technology

Note 10 Clarify VE vascular enhancement technology

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510 (k) Number (if known): K 140959

Device Name:

AcuNav 8F Ultrasound Catheter For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Intended Use:

Catheter is intended for intra-cardiac and intraluminal visualization of cardiac

and great vessel anatomy and physiology as well as visualization of other

devices in the heart of adult and pediatric patients.

	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) *	Other: Harmonic Imaging
Ophtalmic										
Fetal								ļ <u>.</u>		
Abdominal										
Intraoperative (Vascular)										
Intraoperative (Neurological)										
Pediatric		P	Ρ	Р	Р	Р	Р	<u> </u>	Р	
Small Organ (Specify)**										
Neonatal Cephalic	TI				<u> </u>			ļ		
Adult Cephalic								ļ	P	
Cardiac		P	P	Р	Р	Р	Р		Υ	
Trans-esophageal										
Transrectal		<u> </u>								
Transvaginal		<u> </u>		ļ—						
Transurethral	_ _						P			
Intra-Luminal		P	P	Р	Р	Р	Р		F	
Peripheral Vessel	ᆜ	<u> </u>			<u> </u>			ļ.——		
Laparoscopic		ļ. <u>.</u>	<u> </u>	ļ	<u> </u>			<u> </u>		
Musculo-skeletal										
Conventional		1		ļ			 	 	 	
Musculo-skeletal				1					1	
Superficial		↓ _				P	Р —	 	P	
Other (Intra-Cardiac)		Р	P_	P	<u> </u>	<u> </u>		<u> </u>	L	

P=Previously cleared by the FDA K132804

Addit	tional	Com	ments:
/		COIN	1117.119.3

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler.

B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER

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510 (k) Number (if known): K 140959

Device Name:

AcuNav 10F Ultrasound Catheter For Use On ACUSON S1000, S2000, S3000

Ultrasound Systems

Intended Use:

Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other

devices in the heart of adult and pediatric patients.

Clinical Application		Mode of Operation								
	A	В	M	PWD	CWD	Color Doppler	Power (Amplitade) Doppler	Color Velocity Imaging	Combined (Specify) *	Other: Harmonic Imaging
Ophtalmic .										
Fetal		<u> </u>								
Abdominal										
Intraoperative (Vascular)										
Intraoperative (Neurological)										
Pediatric		Р	Р	P	Р	Р	Р		Р	
Small Organ (Specify)**						· · · · ·				
Neonatal Cephalic										
Adult Cephalic										
Cardiac		Р	Р	Р	Р	Р	Р		Р	
Trans-esophageal										
Transrectal								ļ		
Transvaginal										
Transurethral	_1	<u> </u>							р —	
Intra-Luminal		Р	Р	P	Р	Р	Р		P	
Peripheral Vessel			<u> </u>						ļ	
Laparoscopic		<u> </u>							<u> </u>	
Musculo-skeletal										
Conventional		<u> </u>								
Musculo-skeletal				1						
Superficial		<u> </u>					Р —		Р	
Other (Intra-Cardiac)		Р	Ρ	Р	P	Р	<u> </u>	<u> </u>	I	<u> </u>

P=Previously cleared by the FDA K132804

Add	itional	Comm	ienfs:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Colo Doppler, B+PWD+Color Doppler, B+CWD+Color Dop B+Power Doppler.

B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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